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PATENT TRADEMARK OFFICE

Docket No.: 1780/0F908

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Michael Delk; Augustus Felix

Serial No.: 09/481,120

Art Unit: 3763

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Confirmation No.: 5209

Filed: January 11, 2000

Examiner: Kevin C. Simons

For: ELECTRICALLY POWERED SURGICAL IRRIGATOR

October 28, 2002

APPELLANTS' BRIEF

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

This brief is submitted under 37 CFR §1.192 on behalf of Appellants in the above-identified case. A Notice of Appeal was filed on August 27, 2002. This brief is submitted in triplicate, accompanied by the fee set forth in 37 CFR §1.17(f). The Commissioner is hereby authorized to charge any additional fees up to \$500 or credit any overpayment to Deposit Account #04-0100.

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(1) **Real party in interest**

The assignee, C.R. Bard, Inc., is the real party in interest.

(2) **Related appeals and interferences**

There are no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) **Status of claims**

Claims 1-13 are pending in this application. Claims 1-11 have been withdrawn from consideration. Claims 12 and 13 have been rejected under 35 U.S.C. §112, second paragraph, and 35 U.S.C. §103(a) and are the subject of this appeal.

A copy of claims 12 and 13 is provided in the Appendix immediately following this brief.

(4) **Status of amendments**

No amendment was filed after the final rejection.

(5) **Summary of invention**

The invention relates to a battery powered surgical irrigator of the type described in Saravia et al. U.S. Patent No. 5,484,402 and Delk et al. U.S. Patent No. 5,807,313 (Specification, pp 1,2). Such irrigators include a pumping unit which includes a pump and the batteries required to power the pump. In addition, tubing and wiring extend from the pumping unit to the handpiece used by the surgeon to irrigate a surgical site. The pumping unit contains an integral spike so that the pumping unit can be spiked directly into the irrigation bag without the need for tubing between the irrigation bag and pumping unit. In order to simplify the set-up process, the spike is typically enlarged or provided with a rib

or the like in order to support the weight of the pumping unit. Otherwise, the friction between the spike and irrigation bag fitting would be insufficient to support the weight of the pumping unit.

The present invention is shown in Figure 1 in which pumping unit 10 receives liquid from a supply bag 12 that can be forced under pressure through outlet tubing 26 to a handpiece 14. The invention differs from the Saravia et al. and Delk et al. patents by providing a short flexible tube 13 which connects the inlet of pumping unit 10 to the irrigation bag 12. A spike 18 at the opposite end of tube 13 is provided with a lubricant such as silicone. The lubricant makes it relatively easy to insert the spike into the irrigation bag fitting, but it also makes it impossible for the spike to be used to support the pumping unit. Consequently, the invention requires that separate clips 16 (Fig. 2) integrally formed with the pumping unit be provided for attachment to the IV pole 19 on which the irrigation bag is supported.

(6) Issues

Are claims 12 and 13 unpatentable under 35 U.S.C. §103(a) over Saravia (U.S. Patent No. 5,484,402) in view of Jepson (U.S. Patent No. 6,261,266)?

Does the phrase "or the like" render claims 12 and 13 indefinite under 35 U.S.C. §112, second paragraph?

(7) Grouping of claims

Claims 12 and 13 are grouped together.

(8) Argument

a. The Examiner's Rejection (Section 103)

In the Final Rejection (Office Action dated May 31, 2002) the Examiner rejected claims 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Saravia further in view of Jepson.

Saravia shows the basic combination of a pumping unit, handpiece and tubing connecting the outlet of the pumping unit to the handpiece. Saravia also discloses a spike for connecting the pumping unit to the irrigation bag. The Examiner recognizes that Saravia "does not disclose using a lubricant such as a silicone on a spike", but because Jepson discloses the use of a lubricant such as silicone on a spike, the Examiner concluded that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Saravia to include a lubricant on a spike as disclosed by Jepson for reducing friction and thereby lowering the insertion force required into a septum".

b. Saravia, 5,484,402

Saravia teaches a surgical suction irrigator comprising a pumping unit and hand actuatable control. The pumping unit 11 attaches directly to the base of an irrigation liquid supply bag 14. The bag is supported from the horizontal arm 15 of an IV pole 16.

The base of the supply bag includes a conventional luer connector 13; and the pumping unit includes a liquid inlet connector having a hollow spike 12 with an annular rib 12A. The annular rib allows the liquid inlet connector to be forcibly snapfit into the luer connector 13 at the base of the supply bag. Upon connection, the hollow spike pierces the membrane of the supply bag, allowing liquid to flow into the pumping unit.

This connection is strong enough to support the full weight of the pumping unit 11 (and its trailing hose 23 and cable 27) from the supply bag. It can be disconnected only by forcibly pulling the spike and luer connector apart (column 13, lines 17-19). An essential aspect of Saravia's invention is the fact that the pumping unit does not have to be supported by any means other than the connection described. To achieve this, the annular rib on the hollow spike provides for the snapfit, which requires the connection components to be forcibly connected and forcibly separated.

c. Jepson, 6,261,266

Jepson discloses a coupling system wherein a blunt cannula can be inserted into a septum having a pre-slit injection site. Silicone or other lubricant can be used to increase the ease of insertion. The cannula does not pierce the membrane of the septum - it is inserted into a pre-slit opening in the septum.

d. The Present Invention Is Not Obvious

The Examiner's fundamental hypothesis on which the rejection is based is flawed. While it may be the case with many devices that reducing friction is desirable, in the case of Saravia's pumping unit, increasing friction is desirable because the spike is used to support the weight of the pumping unit. In fact, in its preferred embodiment, Saravia includes a circumferential rib which engages a complementary groove in a fitting to provide what is effectively a snap fit between the spike and irrigation bag. As pointed out in appellants' specification, because of the considerable weight of the pumping unit (in the prior art) "the spike must include special support means such as a rib or it must be increased in diameter so as to create a friction fit which will support the unit. Regardless

of which technique is used, the modified spike is relatively difficult to insert into a standard irrigation bag". (Specification, page 3)

In short, the prior art related to the type of irrigation unit which is the subject of appellants' claims 12 and 13 expressly requires greater friction, not less, between the spike and irrigation bag. Thus, the Examiner's argument that it would be obvious to lubricate Saravia's spike is wrong. It would indeed be obvious to lubricate the spike if Saravia taught that ease of insertion of the spike into the bag fitting is desirable, but he teaches precisely the opposite. Ease of insertion is undesirable. Accordingly, as a matter of law, a person having ordinary skill in the art would not have been motivated to lubricate Saravia's spike. Such a combination would destroy the intended purpose of Saravia by compromising the strength of the connection between the liquid supply bag and the hollow spike. Saravia's connection is not intended to be made and broken with ease. Rather, it is forcibly snapfitted together so that it can withstand the strain placed on it by the weight of the pumping unit and associated hose and cable. The application of a lubricant would be directly contrary to Saravia's intended purpose by making it possible for the connection to slip and disconnect when the weight of the pumping unit is applied. *See In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (holding no suggestion to modify prior art invention where the modification would render the invention inoperable for its intended purpose).

Claim 12 also distinguishes over Saravia et al. in requiring "a flexible tube connected at one end to said inlet, and a spike connected to the other end of said flexible tube for connecting said inlet to an irrigation bag". In Saravia et al. (as well as Delk et al.) there is no flexible tube between the pump inlet and the irrigation bag. Rather, the pump inlet

includes a spike so that the pumping unit can be supported directly from the irrigation bag. Because, in applicant's invention, the spike is not used as the means for supporting the pumping unit, it is necessary to provide a flexible tube between the pumping unit and irrigation bag so that both can be mounted on the same IV pole without a need for exact alignment between the two.

Hence, even if the Examiner were correct with regard to the lubricated spike, there is still no counterpart in the claimed combination for the claimed flexible tube connected at one end to the inlet of the pump and containing the spike at the opposite end.

e. "Or The Like" Is Not Indefinite

With respect to the rejection under 35 U.S.C. 112, second paragraph, claim 12 is directed to a surgical irrigator which includes "means for supporting the pumping unit on a pole or the like". The Examiner considers the phrase "or the like" to be indefinite.

A claim is considered not indefinite if a person having ordinary skill in the art would understand the scope of the claim when read in light of the specification and the prior art. The Examiner has not articulated any reason why a person of ordinary skill would have any trouble understanding the scope of claim 12.

Although in most cases, irrigation bags are supported on poles, they can be supported on other structures as well. The terminology "pole or the like" obviously refers to any structure of the type which can be used to support an irrigation bag and this would be apparent to any person of ordinary skill.

In the present invention, a person of ordinary skill could be a nurse or other hospital worker. Given the prevalence of IV poles in hospital settings, these personnel would be extremely familiar with the intended utilities of the poles. See *Ex parte Skuballa*, 12 U.S.P.Q.2d 1570, 1571 (Bd. Pat. App. & Inter. 1989) ("an effective amount" found not indefinite where there existed "fully adequate guidelines as to intended utilities and how the uses [could] be effected"). Hospital personnel would be able to readily ascertain the scope of the phrase "or the like," found in claim 12, as limited to other structures or arrangements that possess the same utility as an IV pole. Accordingly, the Examiner's rejection to claim 12 on the grounds of indefiniteness was improper.

(9) Conclusion

The present invention is not obvious over Saravia in view of Jepson. Applying the lubricant disclosed in Jepson to the spike taught by Saravia would render Saravia's invention unsuitable for its intended purpose. Therefore, the Examiner's rejection under 35 U.S.C. §103(a) is improper and should be reversed with respect to all claims.

The language in claim 12 referencing a pole "or the like" is not indefinite because a person having ordinary skill in the art would understand the scope of the claim to be limited to structures and arrangements possessing the same utility as a pole. Therefore, the Examiner's rejection under 35 U.S.C. §112, second paragraph is improper and should be reversed with respect to all claims.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael J. Sweedler", written in a cursive style.

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Appendix

The following claims are pending in this appeal:

12. (Amended) A surgical irrigator, comprising a pumping unit having an inlet and an outlet, a handpiece and tubing connecting the outlet of said pumping unit to said handpiece, said pumping unit including means for supporting the pumping unit on a pole or the like, a flexible tube connecting at one end to said inlet, and a spike connected to the other end of said flexible tube for connecting said inlet to an irrigation bag, said spike being adapted to penetrate a fitting in said irrigation bag and coated with a lubricant.

13. A surgical irrigator according to claim 12, wherein said lubricant comprises silicone.